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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,831	08/30/2001	Reinhard Ebner	PT049P1	8237

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	8

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/941,831	EBNER ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-22 are pending.

The terms "SEQ ID NO: X" and "SEQ ID NO: Y" and "cDNA included in ATCC Deposit No: Z" in claims 1-22 are improper because the disclosure does not define the terms.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 14-16, drawn to an isolated nucleic acid molecule comprising a polynucleotide selected from the group consisting of: (a) the polynucleotide shown as SEQ ID NO: X or the polynucleotide encoded by a cDNA included in ATCC Deposit No; Z; (b) a polynucleotide encoding a biologically active polypeptide fragment of SEQ ID NO: Y or a biologically active polypeptide fragment encoded by the cDNA sequence included in ATCC Deposit No: Z; (c) a polynucleotide encoding a polypeptide epitope of SEQ ID NO: Y or a polypeptide epitope encoded by the cDNA sequence included in ATCC Deposit No: Z; (d) a polynucleotide capable of hybridizing under stringent conditions to any of the polynucleotides specified in (a)-(c), a vector, host cell, recombinant host comprising the isolated nucleic acid molecule of claim 1, classifiable in class 536, subclass 23.2.

II. Claims 11 and 12 drawn to an isolated polypeptide comprising an amino acid sequence with at least 95% identity to a sequence selected from the group consisting of (a) the polypeptide shown as SEQ ID NO: Y or the polypeptide

encoded by the cDNA, (b) a polypeptide fragment of SEQ ID NO: Y or the polypeptide encoded by the cDNA; (c) a polypeptide epitope of SEQ ID NO: Y or the polypeptide encoded by the cDNA; and (d) a variant of SEQ ID NO: Y, classifiable in class 530, subclass 380.

III. Claim 13, drawn to an isolated antibody that binds specifically to the isolated polypeptide of claim 11, classifiable in class 424, subclass 130.1.

IV. Claim 17, drawn to a method for preventing, treating, or ameliorating a medical condition, comprising administering to a mammalian subject a therapeutically effective amount of the polynucleotide of claim 1, classifiable in class 424, subclass 93.21.

V. Claim 18, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising (a) determining the presence or absence of a mutation in the polynucleotide of claim 1, classifiable in class 435, subclass 6.

VI. Claim 19, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising (a) determining the presence or absence of a mutation in the polypeptide of claim 11, classifiable in class 435, subclass 13.

VII. Claims 20 and 21, drawn to a method of identifying a binding partner to the polypeptide of claim 11, classifiable in class 435, subclass 7.1.

VIII. Claim 22, drawn to a method for preventing, treating, or ameliorating a medical condition, comprising administering to a mammalian subject a therapeutically

effective amount of the polypeptide of claim 11, classifiable in class 514, subclass 2.

The inventions are distinct, each from the other because:

Invention I and Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. Invention I is unrelated from Inventions II and III because the polynucleotides of Invention I are unrelated in chemical structure and function, as well as therapeutic function, from the polypeptides of Invention II and the antibodies of Invention III. Additionally, polynucleotides, polypeptides, and antibodies can be used by materially different methods. Polynucleotides can be used as detection probes, polypeptides can be used for antigen presenting cell priming and antibodies can be used in screening assays, for example. The differences between Invention I and Inventions II and III are further underscored by their divergent classification and independent search status.

Invention I and Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated nucleic acid molecule can be used in several materially different processes as displayed in Inventions IV and V.

Invention I and Inventions VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different mode of operation, function and effect.

Invention II and Inventions VI, VII, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated polypeptide can be used in several materially different processes as displayed in Inventions VI, VII, and VIII.

Invention III and Inventions IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different mode of operation, function and effect.

Invention IV and Inventions V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. Inventions IV and Inventions V-VIII are unrelated because the inventions utilize biologically distinct reagents and function in mechanistically different ways. Methods of utilizing polypeptide for treating, preventing, or ameliorating a medical condition requires different technical considerations and different modes of action than methods of introducing polynucleotide into a cells for treating, preventing, or ameliorating a medical

condition. In addition, the methods in Inventions IV, V, VI, VII, and VIII are not disclosed of capable of use together and have different mode of operation, function and effect. The differences between Inventions IV and Inventions V-VIII are further underscored by their different classification and independent search status.

In addition, if applicants elect Group I, IV or V, a further restriction is required because Groups I, IV, and V detailed above read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Applicant(s) must further elect a single sequence for examination. It is noted that this is a restriction requirement to a single invention and NOT a species election requirement.

Applicant should clearly identify X, Y, and Z for the elected claims.

In addition, if applicants elect Group II, III, VI, VII, or VIII, a further restriction is required because Groups II, III, VI, VII, and VIII detailed above read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Applicant(s) must further elect a single sequence for examination. It is noted that this is a restriction requirement to a single invention and NOT a species election requirement.

Applicant should clearly identify Y for the elected claims.

MPEP 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally

constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Because these inventions are distinct for the reasons given above and the search required for each Group is not co-extensive for any other Group, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER